

THE FUTURE OF
CLINICAL DEVELOPMENT



PRAHEALTHSCIENCES



CDASH IN DE PRAKTIJK

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The relationship



- Layout is a combination of source data and CRF data
- Workflow – data cleaning - SDTM



Combination of Source and CRF data

MEDICATION DOSING

Treatment description:

Single dose oral administration of XXX or placebo as tablet(s) / capsule(s) under fasting conditions

Treatment [Not Submitted]

A ☐ Single dose oral administration of XXX or placebo as tablet(s) under fasting conditions

B ☐ Single dose oral administration of XXX or placebo as tablet(s) under fed conditions

Fasting and other requirements met?

☐ No [Not Submitted]
☐ Yes

Actual time (hhmm)

__ __

EXSTDTC

Actual Dose

__

mg

EXDOSE

Number of tablets / capsules

__

NO in SUPPEX

[Not Submitted]

☐

Administered by

[Not Submitted]

[Not Submitted]

☐

Checked by

[Not Submitted]

Comments

COVAL when RDOMAIN=EX



Physical Examination

Visit Date: Visit Name: DAY -1 P1 (0=planned, >0=unplanned)

PHYSICAL EXAMINATION			
Actual time (hhmm)	<input type="text" value="PEDTC"/>	<div>When No is checked, then PETESTCD=PEALL and PEORRES=NO CHANGE. Yes is not submitted</div>	
Is there a change from previous exam or a new abnormality?		<input type="radio"/> No <input type="radio"/> Yes If yes, please check each item	
		<div>PESTAT=NOT DONE PEREASND=NOT EXAMINED</div>	
Body system / part	No/ Yes/ Not exam.	If yes, give comments	
GENERAL APPEARANCE	<input type="radio"/> <input type="radio"/> <input checked="" type="radio"/> not exam.	<div>Note: If the result is Abnormal then PEORRES=Comment</div>	
	<div>PEORRES when PETESTCD=GENERAL</div>		
SKIN / SUBCUTANEOUS TISSUE	<input type="radio"/> <input type="radio"/> <input type="radio"/> not exam.		
	<div>PEORRES when PETESTCD=SKIN</div>		



Demography

- If composite responses are possible, “No/Yes” questions for each response are preferred to “Check all that apply” questions.
- All code lists displayed in the CRF use or map to current CDISC CT, when available.

Race	<input type="radio"/> American Indian or Alaska Native
	<input type="radio"/> Asian
	<input type="radio"/> Black
	<input type="radio"/> Native Hawaiian or other Pacific Islander
	<input type="radio"/> White
	<input type="radio"/> White + Black
	<input type="radio"/> White + Asian
	<input type="radio"/> Asian + Black
	<input type="radio"/> Other please specify <input type="text"/>

RACE, when more than one race selected, RACE=MULTIPLE and individual responses are RACE1 in SUPPDM RACE2 in SUPPDM

RACEOTH in SUPPDM, when more than one entered, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM



Not Done & Comments

- The “No/Yes – assessment completed” question is preferred to “Check if not done” box
- The general recommendation is that the collection of free text comments is discouraged

LABORATORY ASSESSMENTS - BLOOD		
Actual time of sample (hhmm)	Not Done LBSTAT <input type="checkbox"/>	If not done, specify reason
LB DTC		LBREASND
Comments		COVAL when RDOMAIN=LB



Prior and Concomitant medications

CM = Concomitant Medication

PRA code: TEMPL_RDC_B_NL1
Subject number: Title (short): Template for RDC Bedside eCRF NL
Subject Initials: Sponsor name: PRA
Page Name: PREVIOUS_MEDICATION Sponsor code: ABC-123

Visit Date: [Not Submitted] Visit Name: SCREENING [Not Submitted] (0=planned, >0=unplanned)

PREVIOUS MEDICATION

CMCAT=PRIOR

Did the subject receive any previous medication (prescription or OTC) within the last 60 days? ☐ No ☐ Yes [Not Submitted]

Drug Treatment	Dose per administration	Unit	Frequency	Route	Start date	End date or ongoing
CMTRT	CMDOSE	CMDOSU	CMDOSFRQ	CMROUTE	Start CMSTDTC	End CMENDTC
Indication	CMINDC					
Drug Treatment	Dose	Unit	Frequency	Route	Start	End
Indication						

CMENRF = AFTER when checked



Prior and Concomitant Medications (2)

Visit Date:

[Not Submitted]

Visit Name: OVERVIEW

[Not Submitted]

(0=planned,
>0=unplanned)

CONCOMITANT MEDICATION (DRUG TREATMENT)

CMCAT=CONCOMITANT

Any concomitant drug-treatment reported during study treatment and follow-up?

☐ No
☐ Yes

[Not Submitted]

Note: relation between
CM and AE is described
in RELREC

Drug Treatment	Dose per admini- stration	Unit	Frequency	Route	Start date	End date or ongoing
<input type="text"/> CMTRT	<input type="text"/> CMDOSE	<input type="text"/> CMDOSU	<input type="text"/> CMDOSFRQ	<input type="text"/> CMROUTE	<input type="text"/> Start <input type="text"/> CMSTDTC	<input type="text"/> End <input type="text"/> CMENDTC
Indication <input type="text"/> CMINDC	or AE # <input type="text"/> <input type="text"/> <input type="text"/>			<input type="text"/>	<input type="text"/>	<input type="text"/>
[Not Submitted]						
Drug Treatment	Dose	Unit	Frequency	Route	Start	End
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Indication <input type="text"/>	or AE # <input type="text"/> <input type="text"/> <input type="text"/>			<input type="text"/>	<input type="text"/>	<input type="text"/>

CMENRF=
AFTER when
checked